DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

M2865M

One Montvale Avenue
Stoneham, Massachusetts 02180
(781) 279-1675
FAX: (781) 279-1742

August 13, 1999

WARNING LETTER

NWE-28-99W

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Donna M. Gallagher, M.D.
Cape Cod Radiology Associates, Inc.
66 Lewis Bay Road
Hyannis, MA 02601

RE: Inspection ID – 1053950012

Dear Dr. Gallagher:

We are writing to you because on August 6, 1999, your facility was inspected by a representative of the Commonwealth of Massachusetts, acting in behalf of the Food and Drug Administration (FDA). This inspection revealed a serious regulatory problem involving the mammography at your facility. Under a United States Federal law, the Mammography Quality Standards Act of 1992, your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. The inspection revealed the following level 1 and level 2 findings at your facility:

Level 1: [redacted] QC records were missing for 5 weeks for unit 3, [redacted]

Level 2: The processing speed (using the S.T.E.P. procedure) is greater than or equal to 85, but less than 100 for extended processing: processor [redacted] Other, room darkroom at site Cape Cod Radiology Associates, Inc.

Cape Cod Radiology Associates, Inc.
Hyannis, MA
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The specific problems noted above appeared on your MQSA Facility Inspection Report, which was discussed with you facility at the close of the inspection. Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography. It is necessary for you to act on this matter immediately. Please explain to this office in writing within fifteen (15) working days from the date you received this letter:

- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- equipment settings (including technique factors), raw test data, and calculated final results, where appropriate; and
- sample records that demonstrate proper record keeping procedures, if the findings relate to quality control or other records (Note: Patient names or identification should be deleted from any copies submitted).

Please submit your response to:

Michael J. Leal
MQSA Auditor
U.S. Food & Drug Administration
120 Front Street, Suite 680
Worcester, MA 01608

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at

Cape Cod Radiology Associates, Inc.
Hyannis, MA
August 13,1998

http://www.fda.gov. If you have more specific questions about mammography facility requirements, or about the content of this letter, please feel free to contact Mr. Leal at (508) 793-0422.

Sincerely yours,

John R. Marzilli
District Director
New England District